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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,838	04/27/2001	Aftab Alam	P108904-00002	8708

4372 7590 09/10/2003

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EXAMINER

MOHAMED, ABDEL A

ART UNIT PAPER NUMBER

1653

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/842,838	ALAM, AFTAB	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

ACKNOWLEDGMENT FOR PRIORITY, IDS, STATUS OF THE APPLICATION AND CLAIMS

1. This application is a Continuation-In-Part (CIP) of U.S. application Serial No. 09/223,738, filed 12/13/98, now abandoned, which is a divisional of U.S. application Serial No. 08/965,873, filed 11/17/97, now U.S. Patent No. 5,900,376; and U.S. application No. 09/507,977, filing date 2/22/00, now abandoned, which is a CIP of U.S. application No. 09/249,499, filing date 2/12/99, now abandoned, which is a CIP of U.S. application No. 08/965,873, filing date 11/17/97, now U.S. Patent No. 5,900,376. It is noted that the priority recites that Serial No. 09/223,738 is a divisional of 08/965,873; however, there was no restriction requirement made in the parent application Serial No. 08/965,873. The Information Disclosure Statement (IDS), the references cited therewith on Form PTO-1449 are not provided in the instant application. However, as per Applicant's request, since the cited references were considered previously in the parent application Serial No. 09/223,738; pursuant to 37 CFR § 1.98(d), the references cited in Form Pto-1449 in this application have been considered and signed as requested by Applicant. Claims 1-23 are present for examination.

HEADING FOR NONSTATUTORY DOUBLE PATENTING

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

OBVIOUSNESS-TYPE DOUBLE PATENTING

3. Claims 1-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,900,376 in view of BIO-RAD Catalog of 1993, Life Science Research Products, pages 71-74, See e.g., Bradford assay for Proteins on page 71. Although, the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed invention (Serial No. 09/842,838) is directed to a method of protein preparation of protein sample solution for analysis using an acidic component, a precipitate-forming component, and a salt; and a formulation thereof for a protein assay. The claims of U.S. Patent No. 5,900,376 is directed to an assay method using protein-

precipitating agent comprising an acidic component, a precipitate-forming component and a salt. Both inventions are basically the same. They are made by the same procedure. They use the same composition/formulation with the same concentration for the same purpose. Where the instantly claimed invention is directed to a method of formulating of protein sample solution for analysis and a protein assay while the claims of '376 patent is directed to a method of protein assay using the same composition/formulation of the instantly claimed application. The protein assay of the patent claims result in protein sample solution for analysis, which is employed for a method of total protein assay, and are an obvious variation of the application's claims. Where the present claims recite a method of preparation of protein sample solution for analysis, the same materials and steps are carried out as in the protein assay of the '376 patent. Claims 1-4 and 8-15 of U.S. patent No. 5,900,376 encompass the steps of precipitating a protein by treating a protein solution with an acidic agent followed by addition of precipitate forming components such as deoxycholate and SDS, which are claimed in the instant invention. However, the addition and/or the selection of the appropriate organic solvents, detergent precipitating agent such as specific salts and solvents as well as the addition of polysaccharide for the intended purpose of assaying protein is well known as disclosed in Table I of Bio-Rad. Thus, the patent claims are an obvious variation as the present claimed process is also the assay because one would have combined appropriate reagents to produce colorimetric reactions to identify the proteins (See e.g., the Bio-Rad protein assay which is based on the Bradford dye-binding procedure and is a simple colorimetric assay for measuring total protein

concentration). Therefore, the subject matter claimed in the instant application is set forth in '376 patent claims. Hence, it is within the purview of one of ordinary skill in the art to which this invention pertains to easily adapt the claimed method of preparing of protein solution for analysis and a formulation thereof for protein assay of the instantly claimed application into a method of total protein assay as claimed in '376 patent since both sets of inventions use the same composition/formulation for the same purpose. Therefore, one of ordinary skill in the art would envision both sets of claims as one invention.

CLAIMS REJECTION-35 U.S.C. 112^{2nd} PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 16 and 23 are indefinite and confusing in the recitation "a natural product" and "a common laboratory agent" because the phrases "natural product" and "common laboratory agent" are not defined in the specification or in the claims. The phrases would encompass any natural product as well as any laboratory agent, and as such, the metes and bounds of the claims are not determined.

Claims 2 and 18 are indefinite in the recitation the acronym "SDS". Use of the full terminology at least in the first occurrence would obviate this rejection.

Claim 14 is indefinite and vague in the recitation "...according to Claim 1 wherein the second centrifugation in the step (b) is performed....". There is no second centrifugation in step (b) of claim 1, rather, the second centrifugation in claim 1 is recited in step (d). It is believed to be typographical error. Appropriate correction is required.

CLAIMS REJECTION-35 U.S.C. § 103(a)

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bensadoun et al., (Analytical Biochemistry, Volume 70, pp. 241-250, 1976) taken with Carraro et al., (Biochem. & Biophys. Res. Commun., Vol. 200, No. 2, pp. 916-924, 1994).

Bensadoun et al., disclose like the instantly claimed invention a method of protein precipitation in dilute solution by mixing the protein solution with an acidic agent and/or component such as Trichloroacetic acid (TCA) and then adding or introducing into the mixture of the protein precipitate-forming agent such as sodium deoxycholate and a salt such as sodium chloride (See abstract and materials and methods). Hence, the reference clearly discloses a protein-precipitating agent intended for protein assay comprising an acidic component, a precipitate-forming component and a salt, and a

method of protein precipitation thereof. On Table 1, the reference shows some of the most commonly used reagents such as organic solvents (e.g., ethylene glycol, glycerol, acetylacetone, etc.) and polysaccharides (e.g., sucrose, fructose, mannose, xylose, glucose, etc.) in the analysis and in the purification of biological substances, particularly in the process of Lowry protein determination. Thus, the prior art clearly discloses a protein-precipitating agent comprising an acidic component, a precipitate-forming component and reagents such as organic solvents and polysaccharides and a method of preparation of protein sample solution for analysis thereof intended for the purpose of a protein assay.

The primary reference of Bensadoun et al., differs from claims 1-23 in not teaching the use of specific detergent such as SDS and organic solvents such as acetone and alcohol. However, Carraro et al., teach of a two-step precipitation method that removes free SDS detergent from diluted solutions of proteins, thus, allowing for the recovery and quantification of the proteins themselves. In the method, proteins, which have been solubilized with SDS, are first treated with a solution of potassium phosphate, which serves to precipitate free SDS detergent. The protein-containing supernatant is then treated with a trichloroacetic acid solution and potassium chloride, which serves to precipitate the proteins. The protein content is then determined by the Lowry method, which comprises the steps of adding the protein precipitate to an alkaline copper solution and adding a Folin reagent (See e.g., pages 916-918). Therefore, Carraro et al., teach of a method for precipitating proteins in a solution containing a detergent (i.e., SDS), which comprises the steps of treating a protein solution containing SDS with an acidic component and a salt. Although, the secondary reference of Carraro et al. fail to teach that proteins can be precipitated by the combination of the acidic component with a precipitate-forming component such as

deoxycholate. However, the primary reference of Bensadoun et al., teach of a protein assay in which protein is precipitated by treating the protein solution with a combination of an acidic component such as trichloroacetic acid and sodium deoxycholate.

Therefore, it would have been to one of ordinary skill in the art at the time of the instant invention to precipitate the proteins in the method of Carraro et al., with a combination of an acidic agent and deoxycholate rather than an acidic agent and potassium chloride, since Bensadoun et al., teach that such a combination is another, known effective means to precipitate protein equivalent in function to the combination taught by Carraro et al.

With respect to the use of specific organic solvents such as acetone and alcohol; although, none of the prior art cited disclose the use of organic solvents such as acetone and alcohol; however, as admittedly acknowledged on page 3, last paragraph in the instant specification clearly states "Organic solvents such as acetone and alcohol have been used for precipitation of protein in aqueous solution." Thus, in view of this, it is clear that one of ordinary skill in the art would be able to employ organic solvents such as acetone and alcohol for precipitation of protein. Therefore, in view of the above and in view of the teachings of the prior art, one of ordinary skill in the art would have been motivated to use a composition of a protein-precipitating agent, a method of protein precipitation thereof for a protein assay. Thus, the instant invention's method of preparation of protein sample solution for analysis, protein-precipitating agent comprising an acidic component, a precipitate-forming component and a salt, and a method of protein precipitation thereof for protein assay; which fall within the scope of the prior art protein-precipitating agent and method of protein precipitation thereof would have been prima facie obvious from said prior art disclosure to a person of ordinary skill

in the art at the time the invention was made in the absence of sufficient objective factual evidence or unexpected results to the contrary.


CONCLUSION WITH FUTURE CORRESPONDENCE

6. No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

 Mohamed/AAM

September 6, 2003


CHRISTOPHER S. F. LOW
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